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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,335	04/08/2004	Simon C. Robson	01948/095002	8550

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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,335	ROBSON ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	maf

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-3, drawn to methods of diagnosing a mammal having or at risk of having an autoimmune condition, wherein a reduction in NTPDase biological activity **as determined by mRNA levels** identifies said mammal has having or at risk of having the condition, classified in class 435, subclass 6.

II. Claims 2-3, drawn to methods of diagnosing a mammal having or at risk of having an autoimmune condition, wherein a reduction in NTPDase biological activity **as determined by protein levels** identifies said mammal has having or at risk of having the condition, classified in class 435, subclass 7.1.

III. Claims 2-3, drawn to methods of diagnosing a mammal having or at risk of having an autoimmune condition, wherein a reduction in NTPDase biological activity **as determined by phosphohydrolytic activity** identifies said mammal has having or at risk of having the condition, classified in class 435, subclass 7.1.

IV. Claims 5-6, drawn to methods of diagnosing a mammal having or at risk of having an autoimmune condition,

wherein an increase in P2 receptor biological activity **as determined by mRNA levels** identifies said mammal has having or at risk of having the condition, classified in class 435, subclass 6.

V. Claims 5-6, drawn to methods of diagnosing a mammal having or at risk of having an autoimmune condition, wherein an increase in P2 receptor biological activity **as determined by protein levels** identifies said mammal has having or at risk of having the condition, classified in class 435, subclass 7.1.

VI. Claims 5-6, drawn to methods of diagnosing a mammal having or at risk of having an autoimmune condition, wherein an increase in P2 receptor biological activity **as determined by P2 receptor biological activity** identifies said mammal has having or at risk of having the condition, classified in class 435, subclass 7.1.

VII. Claims 8-12, drawn to methods for identifying a candidate compound for treating, reducing, or preventing an autoimmune condition in a mammal comprising measuring NTPDase *gene expression* **as determined by mRNA levels**, classified in class 435, subclass 6.

VIII. Claims 8-12, drawn to methods for identifying a candidate compound for treating, reducing, or preventing an autoimmune condition in a mammal comprising measuring NTPDase *gene expression* **as determined by protein levels**, classified in class 435, subclass 7.1.

IX. Claims 8-12 and 18-20, drawn to methods for identifying a candidate compound for treating, reducing, or preventing an autoimmune condition in a mammal comprising measuring NTPDase *protein activity*, classified in class 435, subclass 7.1.

X. Claims 14-17, drawn to methods for identifying a candidate compound for treating, reducing, or preventing an autoimmune condition in a mammal comprising measuring P2 receptor *gene expression* **as determined by mRNA levels**, classified in class 435, subclass 6.

XI. Claims 14-17, drawn to methods for identifying a candidate compound for treating, reducing, or preventing an autoimmune condition in a mammal comprising measuring P2 receptor *gene expression* **as determined by protein levels**, classified in class 435, subclass 7.1.

XII. Claims 14-17 and 21-22, drawn to methods for identifying a candidate compound for treating, reducing, or preventing an autoimmune condition in a mammal comprising measuring P2 receptor *protein activity*, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other, for the following reasons:

For related process inventions, the inventions are distinct if (a) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; (b) the inventions as claimed are not obvious variants; and (c) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect. See MPEP § 802.01.

The methods of Groups I-III and Groups IV-VI & X-XII do not overlap in scope because the Group I-III inventions comprise methods for diagnosing a mammal having or at risk of having an autoimmune condition, wherein a reduction in NTPDase biological activity identifies the mammal as having or at risk of having the condition, whereas the Group IV-VI & X-XII inventions comprise methods comprising the measurement of P2 receptor

biological activity. The Group I-III and Group IV-VI & X-XII inventions have a materially different design, mode of operation and/or effect since the Group I-III methods comprise a step of evaluating the activity of NTPDase which mode of action is completely different from that of a P2 receptor. Also the chemical structure, and therefore the chemical properties of NTPDase and the P2 receptor are completely different. Moreover the Group I-III and Group IV-VI & X-XII inventions are not obvious variants because, for example, decreases in NTPDase activity are not necessarily indicative of increases in P2 receptor activity and vice versa. Therefore, the methods are not obvious variants over each other.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The methods of Groups I-III and Groups VII-IX do not overlap in scope because the Group I-III inventions comprise

methods for diagnosing a mammal having or at risk of having an autoimmune condition, wherein a reduction in NTPDase biological activity identifies the mammal as having or at risk of having the condition, whereas the Group VII-IX inventions comprise methods for identifying a compound for treating, reducing or preventing an autoimmune condition in a mammal comprising contacting a cell expressing NTPDase with a candidate compound and measure NTPDase expression/activity in said cell such that a compound which increase said expression/activity identifies the candidate compound as useful for treating, reducing or preventing an autoimmune disorder in a mammal. Thus, the Group I-III and Group VII-IX inventions have a materially different design, mode of operation and/or effect since the Group I-III methods comprise a step of evaluating a decrease in the activity of NTPDase in a mammal and as it relates to a diagnosis in a mammal, and the Group VII-IX inventions comprise contacting cells with candidate compounds and determining how such candidate compounds affect NTPDase activity/expression. The Group I-III and Group VII-IX inventions are not obvious variants because, for example, a method which results in a diagnosis of a disease or condition is not an obvious variation over a method which results in the identification of a compound to treat,

prevent or reduce such a condition. Therefore, the methods are not obvious variants over each other.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The methods of Groups IV-VI and Groups VII-IX do not overlap in scope because the Group IV-VI inventions comprise methods for diagnosing a mammal having or at risk of having an autoimmune condition, wherein an increase in P2 receptor biological activity identifies the mammal as having or at risk of having the condition, whereas the Group VII-IX inventions comprise methods for identifying a compound for treating, reducing or preventing an autoimmune condition in a mammal comprising contacting a cell expressing NTPDase with a candidate compound and measuring NTPDase expression/activity in said cell such that a compound which increases said expression/activity identifies the candidate compound as useful for treating,

reducing or preventing an autoimmune disorder in a mammal. The Group IV-VI and Group VII-IX inventions have a materially different design, mode of operation and/or effect since the Group IV-VI inventions comprise methods utilizing the P2 receptor gene/protein and the Group VII-IX methods comprise measuring the level of expression/activity of the NTPDase gene/protein which have completely difference chemical structures and properties. Moreover the Group IV-VI and Group VII-IX inventions are not obvious variants because, for example, methods involving activity levels of P2 receptor and diagnosis of autoimmune conditions of the Group IV-VI inventions are not necessarily indicative of or suggestive of methods for identifying candidate compounds for such methods drawn to measuring NTPDase activity/expression. Therefore, the methods are not obvious variants over each other.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The methods of Groups IV-VI and Groups X-XII do not overlap in scope because the Group IV inventions comprise methods for diagnosing a mammal having or at risk of having an autoimmune condition, wherein an increase in P2 receptor biological activity identifies the mammal as having or at risk of having the condition, whereas the Group X-XII inventions comprise methods for identifying a compound for treating, reducing or preventing an autoimmune condition in a mammal comprising contacting a cell expressing P2 receptor with a candidate compound and measuring P2 receptor expression/activity in said cell such that a compound which increases said expression/activity identifies the candidate compound as useful for treating, reducing or preventing an autoimmune disorder in a mammal. Thus, the Group IV-VI and Group X-XII inventions have a materially different design, mode of operation and/or effect since the Group IV-VI methods comprise a step of evaluating an increase in the activity of P2 receptor in a mammal and diagnosing a mammal, and the Group X-XII inventions comprise contacting cells with candidate compounds and determining how such candidate compounds affect P2 receptor activity/expression. The Group IV-VI and Group X-XII inventions are not obvious variants because, for example, a method which results in a

diagnosis of a disease or condition is not an obvious variation over a method which results in the identification of a compound to treat, prevent or reduce such a condition. Therefore, the methods are not obvious variants over each other.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The methods of Groups VII-IX and Groups X-XII do not overlap in scope because the Group VII-IX inventions comprise methods for identifying a compound for treating, reducing or preventing an autoimmune condition in a mammal comprising contacting a cell expressing a NTPDase with a candidate compound and measuring NTPDase expression/activity in said cell such that a compound which increases said expression/activity identifies the candidate compound as useful for treating, reducing or preventing an autoimmune disorder in a mammal, whereas the Group X-XII inventions comprise methods for identifying a compound for

treating, reducing or preventing an autoimmune condition in a mammal comprising contacting a cell expressing P2 receptor with a candidate compound and measuring P2 receptor expression/activity in said cell such that a compound which increases said expression/activity identifies the candidate compound as useful for treating, reducing or preventing an autoimmune disorder in a mammal. Thus, the Group VII-IX and Group X-XII inventions have a materially different design, mode of operation and/or effect since the Group VII-IX methods comprise the use of different genes/proteins with different chemical structures and properties. Moreover, the Group VII-IX and Group X-XII inventions are not obvious variants because, for example, methods that affect NTPDase activity are not necessarily indicative of methods that affect P2 receptor activity or suggestive of such methods wherein the methods involve identifying candidate compounds for testing, preventing, or reducing autoimmune conditions. Therefore, the methods are not obvious variants over each other.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The methods of Groups I, IV, VII, & X and Groups II, V, VII, & XI, and Groups III, VI, IX & XII do not overlap in scope because the Group I, IV, VII, & X inventions comprise methods which determine *mRNA levels* in order to either diagnosis a condition or identify a candidate compound, whereas the Group II, V, VII, & XI inventions comprise methods which determine *protein levels* in order to either diagnosis a condition or identify a candidate compound, whereas the Group III, VI, IX & XII inventions comprising methods which determine *protein activity* in order to either diagnose a condition or identify a candidate compound. Thus, the Group I, IV, VII, & X and Group II, V, VII, & XI, and Group III, VI, IX & XII inventions have a materially different mode of operation. Moreover, the Group I, IV, VII, & X, Group II, V, VII, & XI, and Group III, VI, IX & XII inventions are not obvious variants because, for example, methods which affect NTPDase protein activity are not necessarily indicative of or suggestive of methods which affect NTPDase mRNA expression levels. Furthermore, methods which

affect P2 receptor mRNA expression levels are not necessarily indicative of P2 receptor protein levels or P2 receptor protein activity. Therefore, the methods are not obvious variants over each other.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 1 links inventions I-III. Claim 4 links inventions IV-VI. Claim 7 links inventions VII-IX, and claim 13 links inventions X-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 4, 7 and 13. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR

1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

August 8, 2006

DAVID GUZO
PRIMARY EXAMINER